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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/534,660 | 11/28/2005 | Gunther Harth | 51326-00005 NAT | 6518 |
| 45200 | 7590 | 09/12/2008 | | |
| K&L Gates LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319 | | | EXAMINER OLSON, ERIC | |
| | | | ART UNIT 1623 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/534,660 | Applicant(s) HARTH ET AL. | |
| | Examiner Eric S. Olson | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7,10-13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7,10-13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted May 7, 2008 wherein claims 5, 7, 10, 12, 13, 15, and 16 are amended. This application is a national stage application of PCT/US03/36705, filed November 17, 2003, which claims benefit of provisional applications 60/426502, filed November 15, 2002, and 60/430407, filed December 2, 2002.

Claims 5, 7, 10-13, 15, and 16 are pending in this application.

Claims 5, 7, 10-13, 15, and 16 as amended are examined on the merits herein.

The declaration of Marcus Horowitz and Owen Griffith under 37 CFR 1.132, submitted May 7, 2008, has been fully considered and entered into the record. The declaration is discussed further below as it relates to the rejections of record in the previous office action.

Applicant's declaration and arguments, submitted May 7, 2008, with respect to the rejection of instant claims 5, 7, 10-13, 15, and 16 under 35 USC 103(a) for being obvious over US 6013660 in view of Griffith et al. in view of Harth et al., has been fully considered and found to be persuasive to remove the rejection as the declaration demonstrates an unexpected selectivity of alpha-ethyl-L-methionine-sulfoximine for bacterial glutamine synthetase over the mammalian synthetase, which would be expected to lead to reduced side effects in a mammalian subject. Therefore the rejection is withdrawn.

Applicant's declaration and arguments, submitted May 7, 2008, with respect to the rejection of instant claims 5, 7, 10-13, 15, and 16 under 35 USC 103(a) for being obvious over Harth et al. in view of Griffith et al., has been fully considered and found to be persuasive to remove the rejection as the declaration demonstrates an unexpected selectivity of alpha-ethyl-L-methionine-sulfoximine for bacterial glutamine synthetase over the mammalian synthetase, which would be expected to lead to reduced side effects in a mammalian subject. Therefore the rejection is withdrawn.

Applicant's declaration and arguments, submitted May 7, 2008, with respect to the rejection of instant claims 5, 7, 10-13, 15, and 16 under the doctrine of obviousness-type double patenting for claiming the same invention as US 6013660 in view of Griffith et al. in view of Harth et al., has been fully considered and found to be persuasive to remove the rejection as the declaration demonstrates an unexpected selectivity of alpha-ethyl-L-methionine-sulfoximine for bacterial glutamine synthetase over the mammalian synthetase, which would be expected to lead to reduced side effects in a mammalian subject. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 7, 10, 12, 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamler et al. (US patent 6057367, cited in PTO-892)

Stamler et al. discloses a method of killing or reducing the growth of pathogenic microbes in mammals such as humans by selective manipulation of nitrosative stress. (column 2 lines 32-40) Pathogenic microbes include mycobacteria such as *Mycobacterium tuberculosis*, *Mycobacterium leper*, and *Salmonella typhi*. (column 3 lines 7-18) This method includes administering compounds such as alpha-alkyl-S-alkyl homocysteine sulfoximines, particularly racemic DL,RS mixtures or the single L,S diastereomer. (column 14 line 65 – column 15 line 12) These compounds are described as having an alpha alkyl of 2-8 carbons, which meets the definition of R₁ in the instant claims, and an S-alkyl of 1 to 10 carbon atoms. One skilled in the art would at once envisage these compounds as including the specific S-methyl compound which is a methionine sulfoximine according to the instant claims. Therefore the claimed invention is anticipated by Stamler et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler et al. (US patent 6057367, cited in PTO-892) in view of the Merck Manual of Diagnosis and Therapy, Seventeenth Edition. (Reference included with PTO-892, herein referred to as Merck)

The disclosure of Stamler et al. is discussed above. Stamler et al. does not disclose a method further comprising administering isoniazid.

Merck discloses that Isonazid is a commonly used drug for the treatment of tuberculosis and is used in combination with other therapeutic agents. (p. 1196, table 157-6, p. 1197 left column second paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to co-administer the therapeutic compounds of Stamler et al. with Isonazid. One of ordinary skill in the art would have been motivated to combine these two compounds because they are both shown in the prior art to be useful for the same purpose, namely treating *Mycobacterium tuberculosis* infection. One of ordinary skill in the art would reasonably have expected success because combining two known compositions that are disclosed in the art to be useful for the same purpose is well within the ordinary and routine level of skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

Art Unit: 1623

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5, 7, 10, 12, 13, 15, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6057367. (Cited in PTO-892, herein referred to as '367) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6 of '367 anticipate the claimed invention. In particular, these claims are directed to a method for treating a microbial infection by administering an inhibitor of glutathione synthesis that is an alpha-alkyl-S-alkyl homocysteine derivative having an alpha alkyl group that is 2-8 carbons and an S-alkyl group that is 1-10 carbons. One skilled in the art would at once envisage these compounds as including the specific S-methyl compound which is a methionine sulfoximine according to the instant claims. Pathogenic microbes are disclosed in the specification to include mycobacteria such as *Mycobacterium tuberculosis*, *Mycobacterium leper*, and *Salmonella typhi*. (column 3 lines 7-18) Thus claims 1-6 of '367 anticipate the claimed invention.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
9/10/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623